UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

OFFICE OF
SOLID WASTE AND EMERGENCY
RESPONSE

JAN 11 2007

MEMORANDUM

SUBJECT: Response to OIG Report No. 2007-P-00002 "EPA Needs to Plan and Complete a Toxicity Assessment for the Libby Asbestos Cleanup"

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Attached is the U.S. Environmental Protection Agency's (EPA or Agency) response to the Office of Inspector General's (OIG) above-referenced report regarding the Agency's ongoing cleanup of the Libby Asbestos Superfund site in Montana. EPA is aware of and has been addressing the issues identified in the report. EPA is committed to conducting a comprehensive amphibole asbestos toxicity assessment and to reviewing and revising, where necessary, statements made regarding living with or handling asbestos. Also, we will continue to communicate our findings to affected communities. However, EPA disagrees with the manner in which the OIG has characterized EPA's work.

EPA is most concerned that readers of the report will be left with the impression that EPA is not working to protect the health of the people of Lincoln County. According to the report, the OIG was asked by both Montana Senators to review EPA's efforts to clean up amphibole asbestos contamination in Libby. Given this charge, the report would have been more complete with a description of the extensive cleanup activities that have been underway since 2000. EPA has performed 794 residential and commercial property cleanups, and removed more than 400,000 tons of contaminated soil and debris. EPA has demonstrated an unwavering commitment to this cleanup and has reduced exposure to asbestos throughout the Libby community. Although not acknowledged in the OIG report, the Agency for Toxic Substances

and Disease Registry in its 2003 Public Health Assessment (PHA) for the Libby Montana site stated clearly that "The cleanup actions undertaken by EPA are protective of public health." While we agree with the PHA that the cleanup actions are protective, EPA has communicated to the public that it may need to return to properties to perform additional work based on the outcome of ongoing risk assessment activities.

EPA has not ignored the need for better science to support a risk assessment at Libby. There are a number of activities underway, including a toxicological review for noncancer effects of asbestos and a reassessment of the asbestos cancer health assessment. EPA is also committed to conducting a comprehensive toxicity assessment of the Libby amphibole, which will include animal toxicity testing. Regarding the second recommendation, EPA had already begun to address inconsistencies in its public outreach documents prior to them being noted in the report.

Detailed comments that outline our concerns with the OIG report are attached.

Response of the U.S. Environmental Protection Agency
to the Office of Inspector General Report
***"EPA Needs to Plan and Complete a Toxicity Assessment for the Libby Asbestos Cleanup"* No. 2007-P-00002**

This is the U.S. Environmental Protection Agency's (EPA or Agency) response to the Office of Inspector General's (OIG) above-referenced "Quick Reaction" report regarding the Agency's ongoing cleanup of the Libby, Montana Superfund site. The report concluded that EPA needed to complete a toxicity assessment of amphibole asbestos for the Libby, Montana Superfund site; and EPA should ensure consistent safety information in asbestos-related documents intended for the public.

1. EPA does not agree with the manner in which the OIG characterized EPA's work. The report does not recognize that EPA has been working aggressively to protect the health of the people of Libby.

The OIG reviewed EPA's efforts to cleanup up amphibole asbestos contamination in Libby, Montana. However, the report should have documented and explained the extensive cleanup efforts that have been underway since 2000. Of most concern to EPA is the impression left that EPA is not aggressively working to protect the health of the people of Lincoln County.

EPA has demonstrated its commitment to this cleanup. In 2000, EPA started removal cleanup actions in Libby. Given that Libby's residents were exposed to high levels of amphibole asbestos, EPA chose to take early cleanup action without waiting for completion of all of the multi-year exposure and toxicity assessments that would ultimately be needed to select long-term remedial actions. While the long-term cleanup plan will be based upon a site-specific risk assessment, which will include exposure and toxicity assessments, EPA worked to reduce the asbestos exposure experienced by the residents of Libby by immediately starting cleanup actions. EPA's cleanup actions to reduce exposure to asbestos contamination were supported by the Agency for Toxic Substances and Disease Registry (ATSDR) in the 2003 Public Health Assessment (PHA) of the Libby site, which concluded that EPA's initial cleanup actions were protective of public health. Through FY 2006, EPA has spent $154 million at the site and has completed 794 residential and commercial property cleanups. EPA has removed more than 400,000 tons of soil and debris contaminated with high levels of amphibole asbestos and reduced exposure to additional amphibole asbestos remaining near the surface by covering it with clean soil. These actions have greatly reduced asbestos exposure in the community.

EPA will continue to conduct the assessments that are necessary to develop a protective, long-term cleanup remedy. EPA has committed to conducting toxicity studies specific to the Libby amphibole. Toward this end, EPA scientists, in consultation with ATSDR, are developing detailed plans and a schedule for the next phase of risk assessment, which

will include the toxicity studies. In particular, we are planning a meeting in January 2007 of government scientists from inside and outside the Agency to discuss this effort.

While we do not agree with the way the OIG characterized EPA's work, EPA is fully committed to conducting the necessary toxicity and other assessments to develop a long-term cleanup remedy that will protect the health of the citizens of Lincoln County. As to the second recommendation, regarding public outreach documents, EPA is already working to revise as necessary any statements regarding living with or handling asbestos.

2. The OIG did not recognize one of the principal findings of the ATSDR in its Public Health Assessment of Libby that concludes: "The cleanup actions undertaken by EPA are protective of public health."

The OIG references an ATSDR Public Health Assessment for the site, which was issued in 2003. However, the OIG presents an incomplete analysis of this assessment and only focuses on a single, partial recommendation in the PHA that more research is needed, including a toxicological investigation of the risks associated with low-level exposure to asbestos. While EPA agrees that additional research is needed, the OIG did not recognize one of the principal, if not most important, findings of the 2003 PHA regarding the initial cleanup activities at the Libby, Montana site: "The cleanup actions undertaken by EPA are protective of public health."

The OIG also states on page 2: "EPA has no way to determine whether the initial removals sufficiently reduced the risk that Libby residents would become ill or get sicker. EPA personnel informed us that this is the case because EPA had not completed an amphibole asbestos risk assessment." These statements are not balanced by the fact that EPA's actions have reduced risks in the community by greatly reducing the exposure. This is supported by the finding of ATSDR in its Public Health Assessment. The activities being planned for the future will help determine if this risk reduction has been sufficient.

3. The Report mischaracterizes the ATSDR Public Health Assessment on which it relies.

EPA in the ATSDR PHA is specifically directed to "continue to investigate and clean up the site to reduce or remove contaminating sources of Libby asbestos." (pg.1) The ATSDR PHA provides no direction to EPA to conduct toxicity studies as suggested by the OIG; the PHA instead offers a general undirected statement of the need for better science regarding this type of asbestos and related diseases. The PHA does not specifically state that EPA should conduct these studies. The PHA does say "[m]ore research is needed, specifically: toxicological investigation of the risks associated with low-level exposure to asbestos, especially Libby asbestos; clinical research on treatments for mesothelioma and asbestosis; and epidemiologic studies to better characterize the link between exposure to asbestos and disease."

Also on page 1, the OIG report misquotes ATSDR's definition of toxicology as "the study of the harmful effects of chemicals on humans and animals." In fact, in the Libby

PHA, ATSDR defines toxicology as "the study of the harmful effects of substances on humans or animals" (emphasis added). This is an important distinction, because, as noted below, the incorrect use of "and" forms the basis for OIG's conclusion that EPA cannot rely on human studies without the support of animal studies.

4. The Report is inaccurate in its statements about the science of risk assessment and its interpretation of EPA risk policies.

The report contains numerous inaccuracies and misstatements about the science of risk assessment and the practices of EPA in developing risk assessments. This is particularly so in the section titled "OSWER Studies of Libby Asbestos," which is confusing and contradictory. Several examples illustrate EPA's concerns.

The OIG report states that "a toxicity assessment (for Libby) was proposed but denied..." In fact, EPA's ORD initiated a non-cancer toxicity assessment for asbestos in 2003. ORD began planning for a reassessment of cancer toxicity in 2006. The Office of Solid Waste and Emergency Response is developing an interim risk methodology for cancer toxicity assessment that may be used until the ORD reassessment is completed. It is important to recognize that toxicity assessment, as defined in the Risk Assessment Guidance for Superfund (RAGS) Part A (Chapter 7), is composed of two steps: hazard assessment and dose-response assessment. The OIG points to the use of epidemiologic information as a reason that the toxicity assessment has not been completed when in fact the evaluation of all available data is an essential component of this ongoing assessment. The OIG report discusses the role of toxicology and epidemiology in a toxicity assessment but does not accurately describe these scientific disciplines and their role in preparing toxicological assessments for Superfund sites.

Toxicological assessment of a substance uses available information on a substance to understand its potential adverse effects. This effort may include both laboratory animal toxicity testing and human epidemiologic studies. EPA conducts toxicological assessments, including hazard characterization and dose response assessment, to develop reference concentrations and inhalation unit risks which would be used to estimate risk from airborne exposures. As discussed above, EPA is already progressing on these assessments for asbestos, to include the Libby amphibole. Although additional animal testing may be useful, it would not be a shortcoming to conduct a health assessment on available information without additional animal testing. EPA's March 2005 *Guidelines for Carcinogen Risk Assessment* favors use of human data where adequate over animal data for quantitative risk assessment.

The OIG cites two seminal Agency technical guidance documents that state a preference for human data when available and of good quality: EPA's March 2005 *Guidelines for Carcinogen Risk Assessment*[1] and EPA's December 2002 *A Review of the Reference*

[1] The 2005 guidance states: "When human data of high quality and adequate statistical power are available, they are generally preferable over animal data and should be given greater weight in hazard characterization and dose-response assessment, although both can be used."

Dose and Reference Concentration Process[2]. The OIG discounts these documents by quoting the disclaimer language EPA uses to ensure the documents are not misconstrued as regulations. Yet the OIG returns to the same guidances they previously dismissed and quotes passages from them. The OIG's analysis is internally contradictory and their positions are not supported by the information they present in their report. As the aforementioned guidance documents indicate, EPA recognizes the value of both epidemiologic and animal toxicity studies and intends to use both in its ongoing assessment of the risks associated with Libby amphibole asbestos.

A final example of the OIG's misunderstanding of the subject matter is when the OIG suggests (pg. 4) that human epidemiological studies involve "perform[ing] toxicity tests on humans." Epidemiologic studies are observational and do not involve intentional exposure of humans as performed in animal toxicity testing.

5. The action called for in the second recommendation, revising public outreach materials, had been initiated before the OIG conducted its review.

The other recommendation in this Quick Reaction report is that EPA evaluate two public outreach documents that advise citizens about how to deal with asbestos in homes. The document prepared for the Libby residents is no longer on the Region 8 web site. EPA took action to address these concerns before the release of the OIG Quick Reaction Report. Our overall message remains consistent – repair and removal of asbestos-containing and asbestos-contaminated materials should be performed by a trained professional. The advice in this document will be updated, and EPA will continue to work to ensure our communications with the public are clear and consistent.

6. The OIG did not recognize that EPA and others are already taking action to improve the science surrounding amphibole asbestos.

The OIG did not fully recognize that developing longterm, protective clean-up levels for Libby asbestos will require a number of scientific activities. EPA has already conducted assessments of asbestos toxicity and is working to refine these assessments. A toxicity assessment for carcinogenic effects of asbestos is available on the Integrated Risk Information System (IRIS) at: http://www.epa.gov/iris/subst/0371.htm. This assessment is the Agency's consensus opinion for the class of minerals known as asbestos, which includes both serpentine and amphibole minerals. However, there are additional uncertainties with its application to the Libby amphibole, and additional data pertinent to Libby have been published since the publication of the assessment. The IRIS cancer assessment will be updated in the future to ensure that it incorporates these and other new studies.

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[2] The 2002 guidance states: "Adequate human data are the most relevant for assessing risks to humans. When sufficient human data are available to describe the exposure-response relationship for an adverse outcome(s) that is judged to be the most sensitive effect(s), reference values should be based on human data."

Additionally, EPA published a Health Assessment Document for Vermiculite (EPA/600/8-91/027) in September 1991, which recognized the presence of Libby amphibole and recommended that these fibers be considered "as capable of creating asbestos-related diseases and they should be regulated accordingly."

In addition, the Office of Solid Waste and Emergency Response (OSWER) is leading an effort to refine its ability to assess carcinogenic risks that may be associated with specific asbestos minerals of different type and fiber size. A draft of this methodology will be submitted to EPA's Science Advisory Board (SAB) for consultation.

EPA is also developing a non-cancer asbestos assessment for IRIS. The current draft of this assessment is based on the review of the current biomedical literature encompassing non cancer effects of asbestos exposure such as pleural toxicity, asbestosis, and respiratory incapacitation. A draft of this assessment will be undergoing internal review in 2007 and, after interagency review, will be submitted to the SAB for external peer review. Separate from the IRIS non-cancer assessment, EPA Region 8 is developing a site-specific reference concentration (RfC) for Libby amphibole, which is currently undergoing internal review. This draft Reference Concentration and the supporting study of individuals exposed to Libby vermiculite-containing asbestos fibers will be reviewed and considered in the non-cancer health assessment.

Finally, to get an independent picture of the full range of ATSDR health activities that are underway in response to the asbestos contamination in Libby, the OIG is encouraged to read: Horton, K. et al. 2006. A Review of the Federal Government's Health Activities in Response to Asbestos-Contaminated Ore Found in Libby, Montana. *Inhalation Toxicology,* 18:925-940.